BioSynchronicity™

External Quality Controls

for C-Sync™ COVID-19 Antigen Test

For use under the Emergency Use Authorization (EUA) only
For use with the C-Sync™ COVID-19 Antigen Test only
For in vitro diagnostic use
For prescription use only

Instructions for Use (IFU)

IVD

Rx only

REF COV9712ACS

INTENDED USE

The C-Sync™ COVID-19 Antigen Test External Quality Controls are to be used exclusively with the C-Sync™ COVID-19 Antigen Test to monitor the entire assay and provide assurance the test is performing within specifications

SUMMARY AND EXPLANATION OF THE TEST

The C-Sync™ COVID-19 Antigen Test Quality Controls are external quality controls formulated specifically to demonstrate the integrity of the cassette and to ensure the reagents are working properly. The Quality Controls consist of 1 SARS-CoV-2 nucleocapsid protein positive control swab, 1 SARS-CoV-2 spike protein positive control swab, and 1 negative control swab.
It is the responsibility of each laboratory or healthcare setting using the C-Sync™ COVID-19 Antigen Test to establish an adequate quality assurance program to ensure the performance of the test kit under its specific locations and conditions of use. The Positive and Negative Controls should be run once with every new lot, every new shipment, and every new user, and quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

MATERIALS PROVIDED

1 Set :

- 1 C-Sync™ COVID-19 Antigen Test Non-Infectious Recombinant SARS-CoV-2 Nucleocapsid Protein Positive Control Swab.
- 1 C-Sync™ COVID-19 Antigen Test Non- Infectious Recombinant SARS-CoV-2 Spike Protein Positive Control Swab.
- 1 C-Sync™ COVID-19 Antigen Test Negative Control Swab.

TEST PROCEDURE

A. TEST PREPARATION

Wear appropriate personal protective equipment and gloves when running the test.

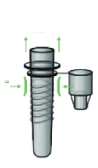
B. NEGATIVE CONTROL SWAB PROCEDURE

Remove a negative Quality Control swab from the package.

1

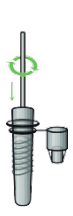
Do not open the External Quality Control swab until just before use. Once opened, the External Quality Control swab should be used immediately.

Remove the foil seal from the extraction buffer tube.



2

Carefully insert the swab inside the vial and plunge it to the bottom. Rotate the swab against the wall of the vial for 10 seconds



3

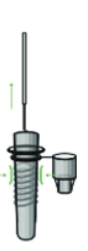
Tightly squeeze and release the bottom of the vial against the absorbent part of the swab. This will make the liquid buffer inside the vial rise and fall. Make sure to cover and wash the absorbent part of the swab. Twirl the swab while squeezing and washing the swab with the buffer. Repeat this squeezing and twirling technique 5 times.

4

Stop squeezing the bottom of the vial and rotate the swab against the wall of the vial for 10 seconds.

5

Remove the swab slowly while squeezing tightly the top part of the vial against the absorbent part of the swab to extract as much liquid as possible from the swab with the goal of drying the swab. Firmly place the dropper cap attached to the vial onto the top of the vial. Make sure the dropper cap is securely in place.



6

Place a C-Sync™ cassette on a flat surface

Add 4 drops of the extraction buffer vial to the sample well of the cassette

7

Read the results at 10 minutes. The tests should not be interpreted past 15 minutes☒

The Control line (C-line) must be visible and the Test line (T-line) must not be visible.
If the C-line is not visible or the T-line is visible, the results are invalid. Do not conduct tests with patients or report results. Contact technical support.

8

C. POSITIVE CONTROL SWAB PROCEDURE for each positive swab

Remove a positive Quality Control swab from the package.

1

Do not open the External Quality Control swab until just before use. Once opened, the External Quality Control swab should be used immediately.

Remove the foil seal from the extraction buffer tube.

2

Carefully insert the swab inside the vial and plunge it to the bottom. Rotate the swab against the wall of the vial for 10 seconds

3

Tightly squeeze and release the bottom of the vial against the absorbent part of the swab. This will make the liquid buffer inside the vial rise and fall. Make sure to cover and wash the absorbent part of the swab. Twirl the swab while squeezing and washing the swab with the buffer. Repeat this squeezing and twirling technique 5 times.

4

Stop squeezing the bottom of the vial and rotate the swab against the wall of the vial for 10 seconds.

5

Remove the swab slowly while squeezing tightly the top part of the vial against the absorbent part of the swab to extract as much liquid as possible from the swab with the goal of drying the swab. Firmly place the dropper cap attached to the vial onto the top of the vial. Make sure the dropper cap is securely in place.

6

Place a C-Sync™ cassette on a flat surface

Add 4 drops of the extraction buffer vial to the sample well of the cassette

7

Read the results at 10 minutes. The tests should not be interpreted past 15 minutes☒

The Control line (C-line) must be visible and the Test line (T-line) must be visible.
If the C-line is not visible or the T-line is not visible, the results are invalid. Do not conduct tests with patients or report results. Contact technical support.

8

EMERGENCY USE AUTHORIZATION

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA certificate of wavier, certificate of compliance, or cretificate of accrediation. this product has been authorized only (to be used with the C-Sync™ COVID-19 Antigen Test) for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

TECHNICAL SUPPORT

Phone: +1 (425) 898-3431
E-mail: support@biosynchronicity.com
www.biosynchronicity.com

MATERIALS REQUIRED BUT NOT PROVIDED

- C-Sync™ COVID-19 Antigen Test
- Timer
- Personal Protective Equipment

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- Exercise the normal precautions required for handling all laboratory reagent
- Do not swallow or inhale.
- Avoid contact with your eyes. if contact occurs, flush with copious amounts of water immediately.

STORAGE AND STABILITY

- Store the Quality Controls between 2°C and 30°C (36°F and 86°F) until use.
- Do not use the Quality Controls beyond the expiration date.
- Do not open the External Quality Controls until just before use. Once opened, the External Quality Controls should be used immediately.

Manufacturer	Consult Instructions for Use
CE mark	For prescription use only
Contains sufficient for <n> test	Do not reuse
Store between 2°C and 30°C (36°F and 86°F)	Do not use if package is damaged
In Vitro Diagnostic device	Use by date
Keep dry	Catalog Number
Keep away from sunlight	

External Quality Controls

for C-Sync™ COVID-19 Antigen Test

BioSynchronicity Corpporation
12835 Bel Red Road, Suite 327
Bellevue, WA 98005, USA

2° C 30° C

Ver: 1-3.05 July 2023